

## REMARKS

With the cancellation of claims 1, 16-18, 20-28, 30, 32-35, 39 and 43-49, and the addition of claims 75-78, claims 2-6, 9-15 and 50-78 are pending.

Claims 1, 16-18, 20-28, 30, 32-35, 39 and 43-49 are cancelled as withdrawn from consideration by the Examiner as a result of the Restriction Requirement dated September 12, 2006.

The new claims 75-78 are supported by the paragraph bridging pages 4 and 5 and page 11, lines 9-15, of the specification.

### Claim Rejections -- 35 U.S.C. 112, First Paragraph

Applicants respectfully traverse the rejections of claims 6, 9-18, and 50-74 as enabled only for a stable pharmaceutical composition comprising high purity torsemide modification II (without trace amounts of torsemide modification I), but not enabled for a stable pharmaceutical composition comprising torsemide modification II containing trace amounts of torsemide modification I. Page 11, lines 9-15 of the specification discloses that the pharmaceutical composition comprising torsemide modification II containing trace amounts of torsemide modification I is stable. Table 1 in page 9 of the specification also shows that the pharmaceutical composition comprising torsemide modification II containing trace amounts of torsemide modification I is stable. In addition, Table 4 in page 14 of the specification demonstrates that for torsemide modification II containing trace amounts of torsemide modification I was stable.

### Double Patenting Rejections

Applicants respectfully traverse the rejection of claims 2-6, 9-15 and 50-74 over the claims of U.S. Patent No. 6,482,417 (US '417) under the doctrine of obviousness-type double patenting. To advance prosecution, however, a terminal disclaimer over US '417 would be filed after the Examiner has held that at least some of the claims are allowable. Applicants request that the obviousness-type double patenting rejection be held on abeyance.

Applicants also respectfully traverse the obviousness-type double patenting rejection of claims 2-6, 9-18 and 52-74 over claims 81, 82 and 85-87 of U.S. Patent No. 6,465,496 (US '496). Applicants note that claims 81, 82 and 85-87 of US '496 are drawn to processes of making torsemide modification II, while the instant claims 2-6, 9-18 and 52-74 are directed to

stable pharmaceutical formulations comprising torsemide modification II. The Restriction Requirement dated September 12, 2006 in the pending application holds that processes of making the stable pharmaceutical formulations belong to a different invention than the stable pharmaceutical formulations. Using similar reasoning, applicants contend that the stable pharmaceutical formulations of the instant claims 2-6, 9-18 and 52-74 would not have been rendered obvious over claims 81, 82 and 85-87 of US '496. This is a reason why the obviousness double patenting rejection over US '496 should be withdrawn.

#### Claim Rejections -- 35 U.S.C. 102

Applicants respectfully traverse the anticipatory rejection of claims 2-6, 9-18 and 52-74 over US '496 because the Examiner took a position that the properties, i.e. high purity and stability, of torsemide modification II recited in these claims would be inherent to the product of the combined method of Examples 9 and 12 since the combined method of Examples 9 and 12 of US '496 is the same method used in the instant application in preparing high purity torsemide modification II. Applicants respectfully disagree. Even if, *arguendo*, one of the Examples before Example 12 in US '496 were combined with and preceded Example 12, the combined process would not necessarily result in the products of claims 2-6, 9-18 and 52-74 because the Example combined with Example 12 can be Example 4, 10 or 11 (which do not start with torsemide modification II), not Example 9. More importantly, as discussed above, US '496 does not disclose explicitly or implicitly combining the methods of Examples 9 and 12 in a sequence. Thus, US '496 does not inherently teach the products of claims 2-6, 9-18 and 52-74.

In addition, US '496 does not disclose a stable pharmaceutical composition comprising high purity torsemide modification II, torsemide modification II containing trace amounts of torsemide modification I, or torsemide modification II at a low water content. The Examiner relied upon column 10, lines 42-44, of US '496 for the anticipatory rejection. The incorporation by reference of RE 30,633 in column 10, lines 35-38, only refers to the preparation of torsemide. However, column 10, lines 42-44, discloses that the new forms of torsemide of the invention described in US '496. Column 1, line 50, of US '496 discloses that torsemide modification II was in the prior art. Thus, the formulation referred to in column 10, 42-44, of US '496 does not contain torsemide modification II. This is another reason why US '496 does not anticipate claims 2-6, 9-18 and 52-74.

Therefore, the anticipatory rejection of claims 2-6, 9-18 and 52-74 over US '496 should be withdrawn.

Claim Rejections -- 35 U.S.C. 103

Applicants respectfully traverse the obviousness rejection of claims 2-5 over Dreckmann-Behrendt (US 5,914,336) in view of Topfmeier et al (RE 34,672). The Office Action relies on the pharmaceutical composition in Example 5 of Dreckmann-Behrendt as comprising 10% torsemide modification II and 45% of a mixture of modification I and III. However, Dreckmann-Behrendt does not disclose or suggest a stable pharmaceutical formulation comprising an effective amount of torsemide modification II and a pharmaceutically acceptable excipient. For instance, Dreckmann-Behrendt does not disclose or suggest a stable pharmaceutical formulation comprising an effective amount of torsemide modification II and a pharmaceutically acceptable excipient, wherein the modification II is of high purity or contains trace amounts of modification I, or the formulation contains a low water content. Topfmeier et al. fails to cure the deficiencies of Dreckmann-Behrendt. Withdrawal of the obviousness rejections over Dreckmann-Behrendt in view of Topfmeier et al. is requested.

Conclusion

If there remains any minor issues that can be resolved with a telephone interview, the Examiner is invited to call the undersigned to discuss it.

If the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee, and any other fees that may be required in relation to this paper, can be charged to Deposit Account 11-0600, referencing Docket No. 01662/51303.

Respectfully submitted,

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